GOVERNMENT OF TELANGANA
ABSTRACT

T.S. – Drugs Control Administration, Hyderabad –Ease of Doing Business, 2017 – Online Application process for Issue / Renewal of Licenses – Orders – Issued.

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HEALTH, MEDICAL & FAMILY WELFARE (C2) DEPARTMENT

G.O.Ms.No.103 Dated:21-6-2017

Read the following:

1) G.O.Rt. No. 233, HM&FW (C2) Dept, dt. 14-3-2017.
2) From the Director I/c, Drugs Control Administration, Hyd, Lr. Rc. No. 17994/E/2015 -1 Dt. 06-6-2017.

***

O R D E R:

The Director, Drugs Control Administration, Hyderabad in his letter 2nd read above, has stated that Telangana was ranked 1st in "Ease of Doing Business" in the year 2016, our effort is to keep up the rank in 2017 also. Department of Industrial Policy and Promotion ("DIPP"), Government of India has communicated the new proposal on "Business Reform Action Plan 2017" and requested the following initiatives to be taken up by Drug Control Administration to ease the process of issuing/renewal of licenses for retail sale, wholesale and manufacturing of drugs:

1) Publish information about the procedure and a comprehensive list of documents on the Department's website.
2) Define clear timelines mandated through the Public Service Delivery Guarantee Act (or equivalent) legislation for approval of complete application.
3) Design and implement a system that allows online application submission, payment, tracking and monitoring without the need for a physical touch point for document submission and verification and mandate that all applications are submitted online.
4) Ensure that the system allows user to download the final signed approval certificate from the online portal.

The system allows:

- Online submission of drug licenses application
- Online submission of documents and verification without the need for a physical touch point
- Online payment of license fees, tracking and monitoring the progress of application
- Allows the users to download the final signed approval certificate from the online portal

2. It should be noted that online application for "Grant of Manufacturing License" is accepted through the online "TS-iPASS portal" at https://ipass.telangana.gov.in/.

3. In this connection, the Director, Drugs Control Administration, T.S., Hyderabad requested the Government to issue an order for the following:

1) Mandating all applications for issuing, renewals and amendments of manufacturing & sales licenses to be submitted online from 1st July, 2017 onwards.
2) Defining clear timelines for the different online services offered by Drug Control Administration as below:

S.No	Item of Works Targeted	*Maximum Response Time (In No. of Working Days)
1	Grant / Renewal of manufacturing licenses (excluding LVP, Sera, Vaccines, r-DNA derived drugs)	14

[P.T.O]

2	Grant / Renewal of Sales (Retail/Wholesale) Licenses	14
3	Grant / Renewal of Approval for Approved Laboratories	10 (after joint inspection of the firm with CDSCO)
4	Approval of Technical Staff	10
5	Recommending for Grant/Renewal of Licenses to Central Licensing Authority, Delhiwith respect to Vaccines and sera; Large VolumeParenterals, r-DNA Derived Drugs, and Blood Banks	10 (after joint inspection of the firm with CDSCO)
6	Effecting Changes in Existing Licenses	10

4. The Director, Drugs Control Administration, T.S., Hyderabad has further stated that, Final License will be issued by the licensing authority within the defined working days of the application submission, provided all the documents, forms, application are in order and after verifying the correctness of the statements made by the applicant as per Rule 65A & Rule 84 AA of Drugs & Cosmetics act, 1940 and rules made their under.

5. The Director, Drugs Control Administration, Hyderabad has also stated that, a well-defined online application procedure (attached as Annexure I), inspection procedure for sales and manufacturing licenses (attached as Annexure II), comprehensive checklist (attached as Annexure III) and Fees Details (attached as Annexure IV) for different applications are also uploaded on the Department's website. The applications shall be made through departmental online portal www.dca.telangana.gov.in.

6. After careful consideration of the matter, the Government hereby agreed the proposal of Director, DCA, T.S., Hyderabad and accordingly, permit the Director, DCA, mandating all applications for issuing, renewals and amendments of licenses to be submitted online from 1st July, 2017 onwards and for manufacturing & sales defining clear timelines for the different online services offered by Drug Control Administration as below:

S.No	**Item of Works Targeted**	***Maximum Response Time (In No. of Working Days)**
1	Grant / Renewal of manufacturing licenses (excluding LVP, Sera, Vaccines, r-DNA derived drugs)	14
2	Grant / Renewal of Sales (Retail/Wholesale) Licenses	14
3	Grant / Renewal of Approval for Approved Laboratories	10 (after joint inspection of the firm with CDSCO)
4	Approval of Technical Staff	10
5	Recommending for Grant/Renewal of Licenses to Central Licensing Authority, Delhi with respect to Vaccines and sera; Large Volume Parenterals, r-DNA Derived Drugs, and Blood Banks	10 (after joint inspection of the firm with CDSCO)
6	Effecting Changes in Existing Licenses	10

7. The Director, Drugs Control Administration, T.S., Hyderabad shall take further follow- up action in the matter.

(BY ORDER AND IN THE NAME OF THE GOVERNOR OF TELANGANA)

RAJESHWAR TIWARI
SPECIAL CHIEF SECRETARY TO GOVERNMENT

To
The Director (I/c), Drugs Control Administration, T.S., Hyderabad

Copy to:
The Pay & Accounts Officer, Hyderabad.
The Principal Accountant General, T.S., Hyderabad.
The State Informatics Officer, NIC, BRK Bhawan, Hyderabad
The HM & FW (F) Department.
The Fin (EBS.V) Dept.
The OSD to C.M.
The OSD to Minister (M&H)
The P.S. to Spl. C.S. to Govt, HM&FW Dept.
SC/SF.

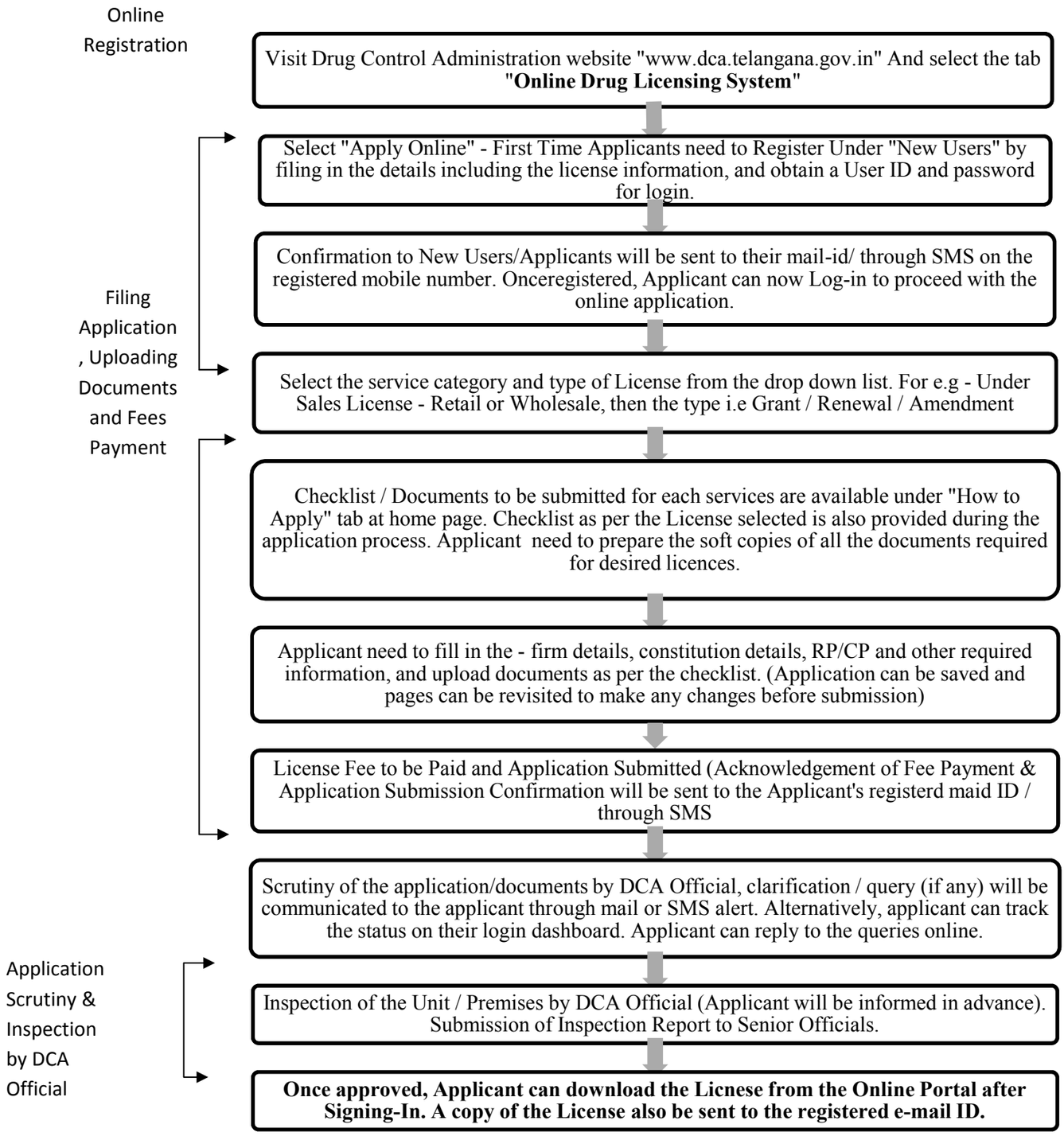
// FORWARDED :: BY ORDER //

SECTION OFFICER

ANNEXURE TO G.O.MS. NO. 103, HM&FW (C2) DEPT, DATED. 21-6-2017

Annexure I

(Online Application Procedure)



RAJESHWAR TIWARI
SPECIAL CHIEF SECRETARY TO GOVERNMENT

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SECTION OFFICER

ANNEXURE TO G.O.MS. NO. 103, HM&FW (C2) DEPT, DATED. 21-6-2017

Annexure II

(Inspection Procedure for Manufacturing & Sales License's Application)

a) The inspector shall verify the following aspects at the time of inspection of the facility for ***grant/ renewal of manufacturing licenses:***

- Production area of the facility to verify the uni-flow of various operations carried out in the respective modules.
- Design of the facility for proper segregation of areas meant for various activities.
- Installation of the required equipment along with the qualification status.
- Purified water generation and distribution system and the status of validation.
- Air Handling Units validations along with the zoning classification (air classification), pressure differentials in various areas of the production modules.
- Material movement and men movement in the production areas to ensure regarding the no chance of cross contamination/ mix up.
- Quality Control laboratory to verify the instruments & calibration status (analytical capabilities of firm).
- Warehousing facilities of the firm for raw materials and finished products.
- Required capabilities of Technical Staff for manufacturing and testing.
- To verify the compliance of the facility with the provisions of Good Manufacturing Practices as per Schedule M (general requirements and specific requirements) and Good Laboratory Practices as per Schedule L-1 of Drugs and Cosmetics Act 1940 and Rules made thereunder.

b) The inspector shall verify the following aspects at the time of inspection of the outlet/premises for ***grant/ renewal of sales licences***as per Rule 64& 65 of Drugs and Cosmetics Act 1940 and Rules made thereunder:

- Area of the outlet to verify the compliance with the statutory limits.
- Capabilities to provide good storage conditions for the drugs stocked in the premises such as racks, refrigerator (for cold storage drugs) etc.

RAJESHWAR TIWARI
SPECIAL CHIEF SECRETARY TO GOVERNMENT

// FORWARDED :: BY ORDER//

SECTION OFFICER

ANNEXURE TO G.O.MS. NO. 103, HM&FW (C2) DEPT, DATED. 21-6-2017

Annexure III

(CHECKLIST)

MANUFACTURING LICENSE

GRANT

FOR GRANT OF LICENCES IN *FORM-25, 25-B (repacking), 28, 28D (LVP, Sera, Vaccines, r-DNA derived drugs), 32*

1. Application (statutory) in form-24/ 27/ 31/ 27D/ 24B

   Duly signed by the Proprietor / Managing Partner / Managing Director/ Person declared as responsible under Sec.34 / Person Authorized by the Board of Directors accompanied by Company Board Resolution.

2. Declaration of the Proprietor / Partners / Directors etc. in Affidavit (as per format) & List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company).

3. Partnership deed (In case of Partnership firms).

4. Self attested Copy of Aadhar card/Passport/Electoral card as proof of residential address of the responsible person as mentioned in the Affidavit at Sl.No. 2.

5. Rent / Lease deed in case of Rental premises.

6. Declaration of the ownership of the premises if premises owned by the applicant firm or Company with the documentary evidence of ownership like Registered sale deed etc and or proof of allotment of the site or building along with latest property tax receipt.

7. Plan and layout of the premises showing the installation of Machinery and Equipment, preferably a Blue Print approved by Licensed Engineer and signed by the applicant who signed in the statutory form.

8. Detailed list of Manufacturing and Analytical Equipment.

9. Application for approval of Technical Staff in the prescribed format with enclosures of consent letter, copies of qualification certificates, experience certificates of proposed technical staff along with earlier approvals, if any, appointment order of the Technical staff.

10. Permission obtained from the Municipal Authorities / Panchayat authorities / Certificate in conformity with Factories Act for construction and starting the Unit & Permission from T.S. Pollution Control Board clearance of the area for setting up the manufacturing facility.

11. Form-46/ Form-46A from Drugs Controller General (India), New Delhi in case of new drugs (Either Bulk drug or Formulation) – New Drugs as defined under Rule 122 E of Drugs and Cosmetics Act and Rules made there under.

Documents to be submitted at the time of inspection of the firm for verification:

Site Master File as per Para 29 of Part I of Schedule M of Drugs and Cosmetics Act, 1940 and rules made there under.

RENEWAL

FOR RENEWAL OF LICENCES IN FORM-25, 25-B (repacking), 28,28D (LVP, Sera, Vaccines, r-DNA derived drugs), 32

1. Application (statutory) in form-24/ 27/ 31/ 27D/ 24B duly signed by the Proprietor / Managing Partner / Managing Director/ Person declared as responsible under Sec.34 / Person Authorized by the Board of Directors accompanied by Company Board Resolution.
2. Copies of drug licences held by the firm.
3. Declaration of the Proprietor / Partners / Directors etc. in Affidavit (as per format) and list of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company).
4. Consent letters of approved technical staff.

Documents to be submitted at the time of inspection of the firm for verification:

Production particulars of the drugs manufactured during the previous licensing period.

LOAN LICENSES

GRANT

FOR GRANT OF LOAN LICENCES IN FORM 25A, 28A, 28DA & 32A.

1. Application (statutory) in form-24A/ 27A / 31A/27DA.
   Duly signed by the Proprietor / Managing Partner / Managing Director/ Person declared as responsible under Sec.34 / Person Authorized by the Board of Directors accompanied by Company Board Resolution.
2. Partnership Deed in case of partnership firm.
3. Declaration of the Proprietor / Partners / Directors etc. in Affidavit (In Prescribed Format) and List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company).
4. Self attested Copy of Aadhar card/Passport/Electoral card as proof of residential address of the responsible person as mentioned in the Affidavit at Sl.No. 2.
5. Letter addressed to the parent firm/Company requesting for consent for availing the manufacturing facilities.
6. Consent letter from the parent firm/Company enclosed with statement of spare capacity
7. Copy of licenses of the parent firm/Company with copy of approved list of the products.(attested by the M.D. / Director of Parent unit/Company)
8. Consent letter of the Technical Staff (Which contain the name of the applicant Unit, and the products) – (in prescribed Format)
9. Copy of the Drug licenses in Form 20B, 21B of the applicant.

RENEWAL

FOR RENEWAL OF LOAN LICENCES IN FORM 25A, 28A 28DA & 32A.

1. Application (statutory) in form-24A/ 27A / 31A/27DA.
2. Duly signed by the Proprietor / Managing Partner / Managing Director/ Person declared as responsible under Sec.34 / Person Authorized by the Board of Directors accompanied by Company Board Resolution.
3. Copies of drug licences held by the firm.
4. Declaration of the Proprietor / Partners / Directors etc. in Affidavit (In prescribed format) and List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company).
5. Consent letters of approved technical staff of parent firm.

Documents to be submitted at the time of inspection of the firm for verification:

Production particulars of the drugs manufactured during the previous licensing period.

REQUIREMENTS FOR ISSUE OF DUPLICATE LIENCE

1. Covering letter indicating the reasons for application for duplicate licence.
2. Copy of Manufacturing Licence.

DOCUMENTS FOR ISSUE OF CHANGE IN DIRECTORS OF THE FIRM (INCLUSION OR DELETION OR CHANGE IN DESIGNATION)

1. Covering letter indicating the details of change.
2. Copy of Manufacturing Licence.
3. Revised list of Directors signed by the firm's director.
4. List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company).
5. Form 32/ Form DIR-12 for inclusion or deletion or change in designation of the director.

REQUIREMENTS FOR ISSUE OF CHANGE IN NAME OR STATUS OF THE COMPANY/FIRM.

1. Covering letter indicating the details of change.
2. Copy of Manufacturing Licence.
3. Certificate issued by the Registrar of Companies.

TEST LICENSE

GRANT

FOR GRANT OFTEST LICENCE IN FORM-29

1. Application (Statutory) in Form - 30 (duly signed or counter signed by the Head of the institution/ Director of the firm or Company)
2. Partnership deed / List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company). (only for the grant of first test licence on the applied premises)
3. Rent / Lease deed in case of Rental premises. (only for the grant of first test licence on the applied premises)
4. Declaration of the ownership of the premises if premises owned by the applicant firm or Company with the documentary evidence of ownership like Registered sale deed etc and or proof of allotment of the site or building along with latest property tax receipt. (only for the grant of first test licence on the applied premises).
5. Plan and layout of the premises showing the installation of Machinery and Equipment preferably a Blue Print approved by Licensed Engineer and signed by the applicant who signed in the statutory form. (only for the grant of first test licence on the applied premises)
6. Self attested Photo copy of Aadhar card/Passport/Electoral card for address Proof of Managing Director / Partners/ Proprietor. (only for the grant of first test licence on the applied premises)
7. List of Manufacturing and analytical equipment. (only for the grant of first test licence on the applied premises)
8. NOC from CDSCO for 'New Drugs' under Rule 122E of Drugs and Cosmetics Act and Rules made thereunder

Bulk Drugs/Formulations

i. Brief Manufacturing procedure of each product

ii. Flow Chart with structural Formula of reactions (for bulk drugs) per Master Formula record and specifications & analytical procedure of applied products with in-house specification claim.

iii. Copies of monographs for drugs with pharmacopoeial specifications other than IP.

RENEWAL

FOR RENEWAL OFTEST LICENCE IN FORM-29

1. Application (Statutory) in Form - 30 (duly signed or counter signed by the Head of the institution/ Director of the firm or Company)
2. Copy of Form-29 issued earlier for the applied drugs.
3. Reconciliation particulars of the drugs manufactured during the previous licensing period under earlier Form-29 issued.

APPROVAL OF TESTING LABORATORY

GRANT

1. Application (statutory) in Form-36.duly signed by the Proprietor / Managing Partner / Managing Director/ Person declared as responsible under Sec.34 / Person Authorized by the Board of Directors accompanied by Company Board Resolution with
2. Partnership Deed in case of partnership firm.
3. Declaration of the Proprietor / Partners / Directors etc. in Affidavit (as per format) & List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company).
4. Self attested Copy of Aadhar card/Passport/Electoral card as proof of residential address of the responsible person as mentioned in the Affidavit at Sl.No. 2.
5. Rent / Lease deed in case of Rental premises
6. Declaration of the ownership of the premises if premises owned by the applicant firm or Company with the documentary evidence of ownership like Registered sale deed etc and or proof of allotment of the site or building along with latest property tax receipt.
7. Plan and layout of the premises showing the installation of Machinery and Equipment, preferably a Blue Print approved by Licensed Engineer and signed by the applicant who signed in the statutory form.
8. Detailed list of Analytical Equipment.
9. Application for approval of Technical Staff in the prescribed format with enclosures of consent letter, copies of qualification certificates, experience certificates of proposed technical staff along with earlier approvals, if any, appointment order of the Technical staff.

RENEWAL

1. Application (statutory) in Form-36.

   Duly signed by the Proprietor / Managing Partner / Managing Director/ Person declared as responsible under Sec.34 / Person Authorized by the Board of Directors accompanied by Company Board Resolution with
2. Copies of drug licences held by the firm.
3. Declaration of the Proprietor / Partners / Directors etc. in Affidavit (as per format)
4. List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company).
5. Consent letters of approved technical staff.

APPROVAL/DELETION OF TECHNICAL STAFF

GRANT

1. List & details of the technical staff to be approved.
2. Details of the Technical Staff for approval in prescribed format (application)
3. Consent of Technical Staff employed in the firm in the prescribed form.
4. Copies of self attested Educational Qualification Certificates & Experience Certificates in the relevant field
5. Copy of Relieving Certificate from the previous employer, attested by the applicant firm.

6. Copy of Appointment and acceptance letters from the employer/applicant firm.

7. *Copy of previous approval of the staff member proposed for deletion.

8. *Relieving letter issued by the firm to the staff member proposed for deletion.

*Documents at Sl.No. 7 & 8 are for applications meant for deletion of technical Staff.

SALES - RETAIL

GRANT

CHECKLIST FOR GRANT / CHANGE OF PREMISES OF RETAIL LICENCE FROM-20, 21 (RETAIL)

1. Statutory form – 19 for licenses in form (20,21).
2. Declaration by the proprietor / Partner / Director / Competent Persons / Regd. Pharmacist with proof of residential address (Present and Permanent) for proof of residential address – Aadhar Card, Pass Port, Driving License, Voter ID.
3. Partnership deed in case of partnership firm/ List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company).
4. In case of Company an Affidavit under Section 34 of Drugs and Cosmetics Act, 1940 on Rs.20/- stamp paper along with copy of its board resolution to this effect signed by one of the Directors of the Company(In prescribed proforma).
5. Special declaration by Registered Pharmacist on Rs.20/- Non-Judicial stamp paper(In prescribed proforma).
6. Self attested copy of Registered Pharmacist certificate (renewal up to date) affixed with latest original photograph and signature of the candidate / original to be produced to the Drugs Inspector at the time of inspection for endorsement.
7. Plan of the premises indicating the carpet area (specifying length and breadth in meters and area in Sq.m) by the Licensed Draftsman / Planner along with the signature of Building owner and the applicant (Prop/ partners / Authorized signatory / Managing Director, etc,.) in a legal size.
8. Declaration of building owner(s) along with his/her/their Photograph(s) (In prescribed proforma). Self attested photocopy of the document showing the proof of ownership of the building owner for the premises to be licensed (E.C / any other legal document showing the present ownership.

SALES - WHOLESALE

GRANT

CHECKLIST FOR GRANT / CHANGE OF PREMISES OF

WHOLESALE

LICENCE

1. Statutory form – 19 for licenses in form (20B,21B).
2. Declaration by the proprietor / Partner / Director / Competent Persons / Regd. Pharmacist with proof of residential address (Present and Permanent) for proof of residential address – Aadhar Card, Pass Port, Voter ID(In prescribed proforma).
3. Partnership deed in case of partnership firm / List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company).
4. In case of Company an Affidavit under Section 34 of Drugs and Cosmetics Act, 1940 on Rs.20/- stamp paper along with copy of its board resolution to this effect signed by one of the Directors of the Company (In prescribed proforma).
5. Special declaration by Registered Pharmacist on Rs.20/- Non-Judicial stamp paper (in case of Registered Pharmacist is appointed as C.P) (In prescribed proforma).
6. Self attested copy of Registered Pharmacist certificate (renewal up to date) affixed with latest original photograph and signature of the candidate (in case Registered Pharmacist is appointed as C.P) / SSC / degree certificate (in case of candidate other than R.P).
7. Plan of the premises indicating the carpet area (specifying length and breadth in meters and area in Sq.m) by the Licensed Draftsman / Planner along with the signature of Building owner and the applicant (Prop/ partners / Authorized signatory / Managing Director, etc,.) in a legal size.
8. Declaration of building owner(s) along with his/her/their Photograph(s). In prescribed proforma. Self attested photocopy of the document showing the proof of ownership of the building owner for the premises to be licensed (E.C / any other legal document showing the present ownership.
9. Experience certificate of competent person.

SALES –RETAIL & WHOLESALE

RENEWAL

CHECKLIST FOR RENEWAL OF LICENSES (RETAIL / WHOLESALE)

1. Statutory form – 19.
2. Declaration by the proprietor / Partner / Director / Competent Persons / Regd. Pharmacist (In prescribed proforma).
3. Affidavit by R.P / C.P on Rs.20/- stamp paper. In prescribed proforma.
4. Self attested copy of Registered Pharmacist certificate (renewal up to date) affixed with latest original photograph and signature of the candidate.
5. Drug licence.

6. List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company).

7. In case of Company an Affidavit under Section 34 of Drugs and Cosmetics Act, 1940 on Rs.20/- stamp paper along with copy of its board resolution to this effect signed one of the Directors of the Company (In prescribed proforma).

HOUSE HOLD REMEDIES LICENSE (RESTRICTED LICENSE)

GRANT

1. Statutory form – 19A for licenses in form – 20A, 21A.
2. Declaration by the Proprietor / Partner / Director with proof of residential address (Present and Permanent) (In prescribed proforma).
3. Partnership deed in case of partnership firm.
4. Plan of the premises indicating the carpet area (specifying length and breadth in meters and area in Sq.m) by the Licensed Draftsman / Planner along with the signature of Building owner and the applicant (Prop/ partners / Authorized signatory / Managing Director, etc,.) in a legal size.
5. Declaration of the building owner(s) (In prescribed proforma).
6. List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company).
7. In case of Company an Affidavit under Section 34 of Drugs and Cosmetics Act, 1940 on Rs.20/- stamp paper along with copy of its board resolution to this effect signed by one of the Directors of the Company. In prescribed proforma.
8. Details of the names of the dealers and their license numbers from whom the applicant will purchase the drugs for sale.
9. Self attested photocopy of the document showing the proof of ownership of the building owner for the premises to be licensed (E.C / any other legal document showing the present ownership.

RENEWAL

1. Statutory form – 19A.
2. Declaration by the proprietor / Partner / Director / Competent Persons /Regd. Pharmacist. *In prescribed proforma.*
3. Drug licence.
4. List of Directors downloaded from MCA website signed by Company Secretary/ Managing Director (In case of company).
5. In case of company an Affidavit under Section 34 of Drugs and Cosmetics Act, 1940 on Rs.20/- stamp paper along with copy of its board resolution to this effect signed one of the Directors of the company. *In prescribed proforma.*
6. Details of the names of the dealers and their license numbers from whom the applicant will purchase the drugs for sale.

CHANGE OF CONSTITUTION

1. Statutory form – 19.
2. Declaration by the Partners with proof of residential address (Present and Permanent)(In prescribed proforma).
3. Dissolution cum partnership deed in case of partnership firm.
4. Special declaration by Registered Pharmacist on Rs.20/- Non-Judicial stamp paper, if being a part of the new constitution or otherwise(In prescribed proforma).

5. Self attested copy of Registered Pharmacist certificate (renewal up to date) affixed with latest original photograph and signature of the candidate.

6. Declaration of competent person if being the part of the new constitution or otherwise (In prescribed proforma).

7. Plan of the premises indicating the carpet area (specifying length and breadth in meters and area in Sq.m) by the licensed draftman / planner along with the signature of Building owner and the applicant (Partners).

8. Declaration of building owner(s) along with his/her/their Photograph(s). In prescribed proforma.

9. Self attested photo copy of the document showing the proof of ownership of the building owner for the premises to be licensed (EC/any other legal document showing the present ownership of the building premises).

10. Original drug license.

11. List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company).

12. In case of Company an Affidavit under Section 34 of Drugs and Cosmetics Act, 1940 on Rs.20/- stamp paper along with copy of its board resolution to this effect signed by one of the Directors of the Company(In prescribed proforma).

CHANGE OF PHARMACIST

1. Statutory form – 19.
2. Declaration by the Registered Pharmacist with proof of residential address (Present and Permanent)(In prescribed proforma).
3. Special declaration by Registered Pharmacist on Rs.20/- Non-Judicial stamp paper (In prescribed proforma).
4. Self attested copy of Registered Pharmacist certificate (renewal up to date) affixed with latest original photograph and signature of the candidate, original certificate shall be produced before Drugs Inspector for endorsement.
5. Drug licence.
6. List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of Company).
7. In case of Company an Affidavit under Section 34 of Drugs and Cosmetics Act, 1940 on Rs.20/- stamp paper along with copy of its board resolution to this effect signed by one of the Directors of the Company(In prescribed proforma).

ISSUE OF DUPLICATE LICENSE

1. Covering letter indicating the reasons for application for duplicate licence.
2. Copy of sales licence

// FORWARDED :: BY ORDER //

SECTION OFFICER

ANNEXURE TO G.O.MS. NO. 103, HM&FW (C2) DEPT, DATED. 21-6-2017

Annexure IV

(FEE Details in Rs)

APPLICATION FEES STRUCTURE – MANUFACTURING LICENCES

Application Form	Licence Form	Grant Application		Renewal Application		Late fee per month	Duplicate Licence fee
		Licence Fees	Inspection Fees	Licence Fees	Inspection Fees		
24	25	6000	1500	6000	1500	1000	1000
24A	25A	6000	1500	6000	1500	1000	1000
24B	25B	500	200	500	200	250	1000
24F	25F	6000	1500	6000	1500	1500	1000
27	28	6000	1500	6000	1500	1000	1000
27A	28A	6000	1500	6000	1500	1000	1000
27C	28C	6000	1500	6000	1500	1000	1000
27D	28D	6000	1500	6000	1500	1000	1000
27DA	28DA	6000	1500	6000	1500	1000	1000
27F	28F	6000	1500	6000	1500	1000	1000
30	29	250					
31	32	2500	1000	2500	1000	400	250
31A	32A	2500	1000	2500	1000	400	250
36	37(Sch C& C1)	-	6000	-	6000	1000	-
36	37(Other than C&C1)	-	1500	-	1500	1000	-

APPLICATION FEES STRUCTURE – SALES LICENCE

Application Form	Licence Form	Grant Application	Renewal Application	Late fee per month	Duplicate Licence fee
		Licence Fees	Licence Fees		
19	20B	1500	1500	500	150
19	21B	1500	1500	500	150
19	20	1500	1500	500	150
19	21	1500	1500	500	150
19C	20F	500	500	250	150
19C	20G	500	500	250	150
19AA	20BB, 21BB	500	500	250	150
19A	20A	500	500	200	150

// FORWARDED :: BY ORDER //

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